In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-451V

(not to be published)

* *	Chief Special Master Corcoran
GERDA ULYSSE, *	
*	Filed: May 19, 2022
Petitioner, *	
v. *	
*	
SECRETARY OF HEALTH *	
AND HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Mark Kim Hellie, U.S. Dep't of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On May 4, 2015, Gerda Ulysse filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to -34 (2012) (the "Vaccine Program").[2] Petition, dated May 4, 2015 (ECF No. 1) ("Pet."); Amended Petition, dated Dec. 7, 2015 (ECF No. 17) ("Amend. Pet."). Petitioner alleges that as a result of receiving a seasonal influenza ("flu") vaccine on October 16, 2013, she suffered a rheumatological injury. Pet. at 1. Petitioner later specified her injury to be dermatomyositis ("DM"). Amend. Pet. at 1.

[1]This Ruling shall be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Ruling will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id.*

[2]The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through -34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to Section 300aa of the Act (but will omit the statutory prefix).

An entitlement hearing was held on December 6, 2021, in Washington, D.C., with the parties appearing remotely. The parties have now submitted post hearing briefs,[3] and the matter is ripe for resolution.

For the reasons set forth below, I find entitlement for the Petitioner.

I. Factual Background

Prior Medical History

Ms. Ulysse (born on August 28, 1962) was at the time of vaccination a licensed practical nurse who worked as a dialysis technician. Ex. 2 at 7; Ex. 13 at 237. Her pre-vaccination history is uneventful—with one relevant exception. Three weeks prior to vaccination (on September 24, 2013), Petitioner saw orthopedist Dr. Eric Freeman for treatment of a history of left knee pain after being referred by her primary care physician, Dr. Howard Grill. Ex. 2 at 9. Dr. Freeman noted that Petitioner's pain was "ongoing progressively." *Id.* Petitioner was positive for possible crepitus,[4] mild effusion (or fluid in the relevant knee),[5] and an x-ray was negative for acute bony abnormality, although she revealed some patellofemoral symptoms. *Id.* In addition, she revealed positive results on a "McMurray Test,"[6] performed to evaluate the presence of a meniscal tear.[7] *Id.*

Dr. Freeman opined, based on Petitioner's presentation and exam, that she was suffering from "left knee possible internal derangement. I am going to recommend that we get her into a course of physiotherapy for strengthening exercises." Ex. 2 at 9. He also proposed her use of a slide-on brace and recommended an MRI if her symptoms did not improve. *Id.*

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[3] *See* Petitioner Post Hearing Brief, dated Feb. 14, 2022 (ECF No. 111) ("Petitioner Brief"); Respondent Post Hearing Brief, dated Feb. 14, 2022 (ECF No. 110) ("Respondent Brief").

[4] Crepitus, according to Respondent's expert, Dr. Robert Lightfoot, is "crackling or creakiness when a joint is moved." Tr. at 137.

[5] Effusion is "the escape of fluid into a part or tissue, as an exudation or a transudation." *Effusion*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15649&searchterm=effusion (last visited May 9, 2022).

[6] As explained by Petitioner's expert, Dr. Tassiulas, the McMurray Test is "to detect ligamentous instability or potential meniscal injury, like a mechanical type of problem in the knee." Tr. at 73. Respondent's expert, Dr. Lightfoot, characterized it as a "maneuver when one has a knee condition that is difficult to diagnose or to nail down as to diagnosis that is done to see if possibly there might be an internal derangement, which would be a piece of torn cartilage or a piece of torn ligament." *Id.* at 135.

[7] A meniscal tear, or torn meniscus is a common knee injury where an individual "forcefully twist[s] or roate[s] [their] knee." *Torn Meniscus*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/torn-meniscus/symptoms-causes/syc-20354818 (last visited May 9, 2022). The meniscus is a cartilage in the knee that cushions between the shinbone and thighbone, when torn is causes pain, swelling, popping, locking up of the knee and other issues. *Id.*

Vaccination and Subsequent Medical Issues

Petitioner received the flu vaccine on October 16, 2013, at her workplace. Ex. 1 at 2. Almost two weeks later, on October 29, 2013, she saw Dr. Grill, reporting that she had felt "blah" after the shot. Ex. 2 at 2; Ex. 21 at 2. Dr. Grill observed no temperature or other outward issues, or any other concerning symptoms, but allowed for the possibility of a post-vaccinal reaction, recommending that Petitioner contact him again if she experienced no change. Ex. 2 at 2.

Ms. Ulysse went back to Dr. Grill in early November, reporting more joint stiffness and aches. Ex. 21 at 2. Blood work performed around this time was negative for liver-related issues or rheumatoid factor (which would have suggested a clear rheumatic explanation for Petitioner's joint complaints). Ex. 2 at 26–27.

Petitioner was subsequently referred to Dr. Benjamin Levine, a rheumatologist, and saw him on November 11, 2013, complaining of bilateral wrist aches for two weeks, worsening with use and associated with swelling. Ex. 11 at 118. She also reported bilateral knee pain for a few months (which if correct would predate the mid-October vaccination) that worsened with use. *Id.* Otherwise, she informed Dr. Levine that a week after vaccination, she had developed a rash on her fingers, palms, and elbows along with throat pain, odynophagia and oral ulcers, and later polyarthralgias, with some medications helping the rash but not the joint pain. *Id.*

Exam at the time of this visit with Dr. Levine revealed no fever or upper respiratory-associated symptoms. Ex. 11 at 118–19. Dr. Levine observed ulcers on Ms. Ulysse's cheeks, with full range of motion in her shoulders, with some mild discomfort, tenderness and swelling in her wrists, tender hyper-pigmented lesions of the palms and fingers with cracked skin, minimal hyperpigmentation of the extensor aspect of the elbows, and normal range of motion in the knees with pain and crepitus. *Id.* at 119–21. Her bilateral upper extremity ("BUE") strength was 5/5. *Id.* at 120. Dr. Levine's assessment included acute onset polyarthralgias and inflammatory arthritis, along with a possible "serum sickness-like reaction" that might be vaccine-related. *Id.* at 121. He also performed additional blood and urinalysis tests at this time, that later showed Petitioner's AST at 20, ALT at 19, and the SED rate at 21 mm—all deemed within normal ranges.[8] Ex. 11 at 124–25.

[8]AST stands for aspartate transaminase, "an enzyme of the transverse class that catalyzes the reversible transfer of an amino group from aspartate to α-ketoglutarate to form glutamate and oxaloacetate, with pyridoxal phosphate required as a cofactor." *Aspartate Transaminase*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4466 (last visited May 2, 2022). ALT means alanine transaminase, "an enzyme of the transferase class that catalyzes the reversible transfer of an amino group from alanine to α-ketoglutarate to form glutamate and pyruvate, with pyridoxal phosphate as a cofactor." *Alanine Transaminase*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=1509 (last visited May 2, 2022). SED is shortened for "skin erythema dose." *SED*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=45211&searchterm=SED (last visited May 2, 2022).

Identification of DM as Diagnosis

Dr. Levine referred Ms. Ulysse for a dermatologic consult, and she saw Dr. Eve Lowenstein for that purpose on November 15, 2013. Ex. 5 at 2. Petitioner again stated that she first began experiencing symptoms within two weeks of receipt of the flu vaccine. *Id.* She reported a variety of symptoms at this time: arthralgias at almost all her joints but ankles; swelling of her hands; headache; plus, shoulders and wrists aching, and some pain with swallowing. *Id.* On exam, she displayed a psoriaform rash on her elbows and knuckles, with patchy erythema on her face. *Id.* DM was included in the differential diagnosis, along with connective tissue lupus, or some kind of drug reaction.

Dr. Lowenstein asked to review Petitioner's prior blood work, and also performed skin biopsies from her elbow, forearm, and left lower and upper thigh. Ex. 5 at 5–6. The lab interpreted the results to reveal "patchy interface dermatitis," among other things, deeming the biopsies to present "unusual" findings that likely represented "a drug eruption with features of connective tissue disease." *Id.* at 5. The lab technician opined (based solely on the arm biopsies) that the diagnostic differential should include lupus, DM, and "the drug-induced forms of these diseases." *Id.* New labs performed to test for other possible explanations (including certain autoantibodies, inflammatory biomarkers, and tests to identify other rheumatic-associated immune disorders, like Sjogren's syndrome) produced negative results. *Id.* at 4.

The requested blood work largely was, in Dr. Lowenstein's words, "normal and negative" of any causal etiologies (other than evidence of a resolved parvovirus infection). Ex. 5 at 7. She proposed that Petitioner's clinical presentation was still "consistent with dermatomyositis"—although this raised the possibility of the need for a paraneoplastic evaluation, to rule out some other, more serious but undiagnosed condition like lymphoma. *Id.* After consideration of the biopsy results, however, Dr. Lowenstein proposed that Petitioner's symptoms were "most likely consistent with either connective tissue disease or erythema multiforme related to a drug." Ex. 5 at 7.

Before this dermatologic consult was completed, Ms. Ulysse went to the South Nassau Community Hospital ("SNCH") Emergency Department on November 18, 2013, with complaints of joint pain and rash for the last three weeks. Ex. 13 at 216. She now reported that the day after her flu shot, she had developed 7/10 aching joint pain and stiffness, with a painful rash on her hands and elbows. *Id.* Exam showed moderate edema of the bilateral hands and wrists, with severe pain on movement but no erythema. *Id.* at 218. She ended up being admitted to the hospital until December 6, 2013, due to her inability to ambulate and lack of improvement from pain relievers. *Id.* at 221; 490–92.

Petitioner subsequently underwent several other evaluations at SNCH that same month. Thus, on November 19, 2013, she had a rheumatology consultation with Dr. Joseph Cohn. Ex. 13 at 172. The history from this visit (which occurred prior to receipt of the skin biopsy results) reveals Petitioner's admission that she had while running injured her left knee a year earlier. *Id.* Otherwise, she again reported that two weeks after the October vaccination she developed a skin rash involving her metacarpophalangeal joints and fingertips, elbow, and thighs that had not resolved, followed by joint pain and swelling of her hands, elbows, shoulders, and knees. *Id.* Dr. Cohn conducted a complete exam, and reviewed Petitioner's prior blood work. Ex. 13 at 173. He expressed concern with Ms. Ulysse's low white blood cell count as possibly reflective of a "diffuse viral eruption" or even an HIV infection but based on the available data proposed a differential that included reactive arthritis and Behcet's syndrome.[9] *Id.*

Ms. Ulysse also had a neurology consultation the same day, at which time she complained of difficulty walking due to pain. Ex. 13 at 236. A peripheral neuropathy was deemed possible due to her reflexes, strength, and sensation, but the performed motor exam was "somewhat limited secondary to pain." Ex. 9 at 57; Ex. 13 at 236. She met with treaters in the hematology/oncology department. She described symptoms comparable to what she had previously reported to other doctors, and it was observed that a progressive drop in her white blood cell count was likely attributable to a reaction to an unidentified acute illness (although other blood testing again produced normal results). *Id.* at 167–70, 261, 265, 270. Proposed diagnoses included some unspecified viral illness, Stevens-Johnson's syndrome,[10] and syphilis. *Id.* at 253.

While hospitalized, Petitioner complained of pain when swallowing. Ex. 13 at 351. In the course of treatment, a flexible laryngoscopy found several white patchy ulcerations in her lower pharynx deemed consistent with thrush versus immune-related inflammation, leading Petitioner to be prescribed anti-fungal medication. *Id.* at 330–31. During this period, evidence of dermatomyositis was noted (in particular via skin lesions), along with joint pain and swelling, but no tenderness or weakness *Id.* at 367. Upon discharge, her diagnoses included dysphagia,[11] polyarthralgia, and herpes lesions. *Id.* at 490.

On December 10, 2013, Petitioner had a follow-up visit with Dr. Lowenstein, at which time she complained of weakness and thrush (deemed attributable to the steroid medications she

[9]Behcet's syndrome or Behcet's disease is a rare disorder that causes systemic blood vessel inflammation. *Behcet's Disease*, Mayo Clinic, https://www mayoclinic.org/diseases-conditions/behcets-disease/symptoms-causes/syc-20351326 (last visited May 2, 2022).

[10]Stevens-Johnson syndrome is "traditionally considered to be a severe form of erythema multiforme." *Stevens-Johnson Syndrome*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111447 (last visited May 2, 2022). The syndrome shows "respiratory prodrome precedes a characteristic mucocutaneous lesions and other symptoms." *Id.*

[11]Dysphagia is difficulty when swallowing. *Dysphagia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15265&searchterm=dysphagia (last visited May 3, 2022).

had been taking) leading to difficulty swallowing. Ex. 5 at 9. Skin biopsies taken from her thighs were consistent with different kinds of dermatitis. *Id.* Dr. Lowenstein again proposed (consistent with her November treatment of Petitioner) that Ms. Ulysse was experiencing paraneoplastic or drug-related DM. *Id.* at 9. Later that same December, Petitioner followed up with Dr. Levine, who noted that the rash on Petitioner's hands had not improved, and that she was now reporting severe shoulder, wrist, and knee pain with morning stiffness that lasted more than an hour. Ex. 11 at 135. Her labs were largely negative, except for some evidence of inflammation biomarkers. *Id.* at 135, 140–41. She had no facial rashes or lesions, no liver enlargement, her hyper-pigmented lesions had improved on her palms and fingers, there was hyper-pigmentations over the bilateral MCPs with skin breakdown, and both knees had normal range of motion with discomfort and crepitus. *Id.* at 137–38. Based upon these observations, Drs. Lowenstein and Levine concurred that Petitioner should undergo a muscle MRI. Ex. 5 at 8.

Before the end of December 2013, Ms. Ulysse had a neurology consultation at SNCH with Dr. Joshua Kugler. Ex. 9 at 20. The exam showed normal strength, and although she displayed ulcers on her hands and buttocks and some inflammatory biomarkers, she now revealed normal white blood cell levels, and other test results they were improved from November. *Id.* at 21–25. Dr. Kugler concluded that there was "[n]o laboratory abnormalities of acute significance, except elevated [liver function tests]." *Id.* at 24.

Treatment in 2014 and Beyond

Ms. Ulysse continued to experience a variety of symptoms and conditions, some of which are associated with her DM, but the subsequent record does not shed significant light on the question of vaccine causation. Thus, as of January 22, 2014, at a follow-up visit with Dr. Levine, Ms. Ulysse's arthralgias and myalgias were improving with medication, but she was showing prominent oral and skin ulcers, the etiology of such was unclear to Dr. Levine since DM would not usually produce this kind of symptom. Ex. 11 at 144, 146, 148. She also continued to obtain treatment for throat and mouth ulcer complaints. *See e.g.*, Ex. 6 at 8; Ex. 7 at 1. Intravenous immunoglobulin ("IVIG") treatment Petitioner was receiving was improving her rash, and her various other symptoms also had diminished, although she complained of tingling and numbness of the left fingertips, with decreased sensation in the first to fourth fingertips and the second right fingertip, that led to a proposed neurologic consultation. Ex. 11 at 17–22.

To that end, Petitioner saw neurologist Dr. Jeffrey Behar on March 18, 2014. Ex. 9 at 17. Her history stated, "likely inflammatory arthropathy, possibly post vaccinal, though unclear, clinically improving." *Id.* The exam had severe local pain to palpation of the wrists, along with the EMG/NCS of the BUE being consistent with carpal tunnel syndrome. *Id.* at 18. A brain MRI showed non-enhancing increased signal intensity in the periventricular white matter in both hemispheres. *Id.* at 11–12, 14. This pattern was not associated with demyelinating disease. *Id.* at

11.

By April, Petitioner's persistent joint pain and recurring lesions led her to again seek emergency treatment, and after another rheumatologic workup she was diagnosed with amyopathic DM versus mixed connective tissue disease. Ex. 15 at 68–69, 87. She sought emergency care on other occasions due to her arthralgias and associated symptoms. Ex. 3 at 28, 323. On May 5, 2014, Petitioner had a follow-up appointment with Dr. Levine for her amyotrophic DM, focusing on the rash proposed to have begun after receipt of the flu vaccine. Ex. 11 at 69–73.

Petitioner has since continued to treat for the same overall constellation of issues, informing treaters of the temporal relationship between vaccination at onset of symptoms in the fall of 2013. Because these later medical records do not shed substantial light on the issue of causation, they are not further discussed.

II. Witness Testimony

A. *Petitioner's Expert: Ioannis Tassiulas, M.D., Ph.D.*

Dr. Tassiulas, a rheumatologist, testified at the hearing and prepared a single, relatively-short expert report. Report, dated, July 29, 2016, filed as Ex. 27 (ECF No. 38-1) ("Tassiulas Rep."). He opined that the flu vaccine could cause DM and did so to Petitioner.

Dr. Tassiulas attended the Aristotle University of Thesaloniki School of Medicine in Greece. Ex. 28 at 2, filed on Aug. 1, 2106 (ECF No. 40-1) ("Tassiulas CV"). He thereafter "joined the NIH for a research fellowship in immunology and rheumatology, where [he] spent 2 ½ years working mainly on projects related to systemic lupus erythematosus and rheumatoid arthritis." Tr. at 5. He later did three years of research doing cytokine signaling for autoimmune diseases at Cornell University, followed by five years of teaching back in Greece on rheumatology. *Id.* at 6. He subsequently returned to the United States, where he was an associate professor at West Chester Medical Center for four years. *Id.*

Dr. Tassiulas then went to Mount Sinai Hospital, where he presently works as an "associate professor of medicine, rheumatology attending, associate program director, and medical director of the Rheumatology Faculty Practice." Tr. at 5. He spends approximately 70 percent of his time on clinical treatment of patients, with the remaining 30 percent on education, clinical trials, and rheumatology fellowship program. *Id.* His clinical practice specifically includes general rheumatology, lung disease, and systemic autoimmune diseases, including DM. *Id.* at 8. He estimates seeing about 30 to 50 patients in a year. *Id.* at 9. In discussing his peer-reviewed articles, books, and other authorship, Dr. Tassiulas stated he has researched or written on "the regulation of autoimmunity and inflammation through cytokines and other immune cell receptors." *Id.* at 7.

He is currently involved in a clinical trial evaluating a cytokine receptor inhibitor as a treatment for lung disease associated with autoimmune processes. *Id.* at 8. He also addressed these topics in books, reviews, lectures, presentations, and abstracts. Tassiulas CV at 8–12.

Dr. Tassiulas began his testimony with a general explanation of autoimmune disease. The immune system "consists of different cells that can recognize invaders, and they can recognize them as nonself and, you know, fight them off or can recognize transformed cells and kill them." Tr. at 41. Autoimmune diseases occur when the immune system aberrantly responds to self proteins instead of recognizing them. *Id.* at 42. This causes "the development of inflammation driven by different mechanisms, driven by autoantibodies, driven by inflammatory cells, by lymphocytes, and the development of inflammation in different organs." *Id.* '

DM, Dr. Tassiulas explained, is believed to be the product of autoimmune-mediated inflammation occurring in the muscles and the skin (sometimes also involving the lungs), and can be the result of a combination of environmental factors, a genetic predisposition, and some specific pathologic process. Tr. at 42–43; Tassiulas Rep. at 1. Dr. Tassiulas gave a list of the common classifications used to determine DM, including muscle weakness and cutaneous manifestations, adding that a muscle biopsy or EMG testing[12] can confirm the diagnosis (although Petitioner's case was here not confirmed in this manner). Tassiulas Rep. at 2; Tr. at 14.

Onset of DM is usually acute and "characterized by malaise, fatigue, and not so much muscle pain, but muscle weakness, and especially proximal muscle weakness." Tr. at 12. There are different forms of DM depending on its presentation or evolution. Tr. at 47 (discussing M. Dalakas, *Inflammatory Muscle Diseases*, 372 New England J. Medicine 1734, 1735 (2015), filed as Ex. 27, Tab A (ECF No. 38-1) ("Dalakas")). In its early stages, individuals experience myalgias and muscle tenderness (except in the case of "amyopathic" DM), but often little muscle weakness. Tassiulas Rep. at 2; Tr. at 49. DM affects the joints of the wrists, knees, and hands, with symptoms characterized by arthralgias and arthritis, but can have an impact on the lungs as well. Tr. at 48–50; Dalakas at 1734. It can result in "Gottron papules" (which he defined as "violaceous flat-topped papules and plaques located over the dorsal aspect of interphalangeal or metacarpophalangeal joints"), eyelid rashes, cutaneous vasculitis causing digital ulcerations, and other skin rashes that cause puffy hands and ulcers. *Id.;* Tr. at 13; Dalakas at 1735. It peaks among the general population two times: in childhood (when it is referred to as juvenile dermatomyositis (JDM")), and when individuals are in their 40s and 50s. Tr. at 26–27.

[12]EMG testing is also called electromyography which is a technique that records "the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." *Electromyography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited May 9, 2022). These tests may be done by "surface electrodes, needle electrodes, and devices for amplifying, transmitting, electromyograph." *Id.*

Dr. Tassiulas admitted that generally the cause of DM is unknown (except when it is attributable to malignancies, specifically cancer). Tr. at 81–82. But he also proposed a number of possible environmental triggers for DM. Certain kinds of UV light, for example, are "known to drive inflammation in the skin in patients with lupus or with dermatomyositis." *Id.* at 44. In addition, DM can be caused by infections, smoking, certain medications, and vaccines. *Id.* at 20, 44; H. Orbach & A. Tanay, *Vaccines as a Trigger for Myopathies*, 18 Lupus 1213, 1213 (2009), filed as Ex. 27, Tab B (ECF No. 38-1) ("Orbach"). Orbach specifically identified "hepatitis B vaccine and the BCG vaccination against tuberculosis . . . [with] sporadic cases after vaccination against tetanus, diphtheria," along with a single case of flu vaccine-caused DM. Tr. at 50; Orbach at 1214.[13] In regard to Petitioner's case, the only possible environmental factors (besides the flu vaccine) possibly relevant were sun exposure and infections. *Id.* at 45.

Ms. Ulysse, Dr. Tassiulas proposed, was properly diagnosed with DM, although he allowed there was some ambiguity as to the exact subtype involved. Her primary complaints initially included joint paint, fatigue, skin rashes, and oral ulcers. Tr. at 79. Muscle weakness, by contrast, was not a predominant symptom, and testing even revealed only minor elevations of certain enzymes associated with the problem—but in Dr. Tassiulas's view "the primary thing with dermatomyositis are the skin findings, and this is her case." *Id.*; *see also* Tr. at 13. Ms. Ulysse was also suffering from Gottron's papules and heliotrope rashes, which Dr. Tassiulas deemed more supportive of an amyopathic dermatomyositis diagnosis. *Id.* at 17. In the end, he agreed the medical record included this as the specific diagnosis, although he observed that Petitioner also displayed some muscle inflammation and dysphasia. *Id.* at 18–19.

DM has been proposed to be autoimmune in nature, and Dr. Tassiulas commented on the evidence from Petitioner's history that was consistent with her experiencing an autoimmune process. It is well-understood in medical science that a number of infectious processes could later cause the rise of a secondary autoimmune disease, such as rheumatic fever occurring in the wake of a streptococcal pharyngeal infection, as the immune system (in fighting the infection) aberrantly causes a cross-reaction. Tr. at 28–29. The same could be true of DM. There are also some autoantibodies thought to be potentially associated with DM (and thus might be driving the disease process), although their absence is not exclusionary for the diagnosis, and can in fact be detected only 40 to 60 percent of the time. Tr. at 14, 22–23. In Petitioner's specific case, one such autoantibody was identified in testing, but only "a couple years after her presentation." *Id.* at 14. In addition, a lower extremity MRI performed on Petitioner did show inflammation (*Id.*), and she displayed a decreased white blood cell count that Dr. Tassiulas deemed "not uncommon to see in different autoimmune—systemic autoimmune syndromes." *Id.* at 17–18. However, he acknowledged that this finding was likely explained by her underlying illness rather than standing

[13]The one case report involving the flu vaccine referenced in Orbach is the same case report relied on by Petitioner in this case. *See* F. Jani et al., *Influenza Vaccine and Dermatomyositis*, 12 Vaccine 1484 (1994), filed as Ex. 27, Tab G (ECF No. 38-1).

as evidence of an autoimmune process. *Id.* at 18.

Dr. Tassiulas next put forth some specific mechanistic theories for how an autoimmune process might later manifest as DM. In particular, he mentioned three mechanisms: molecular mimicry, production of interferons (a cytokine that serves a messenger function in immune responses),[14] and wild infection. Tr. at 31. He later admitted that some of them could be connected; for example, a pathologic disease process could feature *both* a molecular mimicry-driven cross-reaction and cytokine upregulation, depending on the process's stage. *Id.* at 59. He maintained that medical literature existed to provide reliable support for each. *Id.* at 31.

Molecular mimicry can occur when amino acid sequences are homologous between a vaccine's components and structures in the human tissue. Antibodies produced by the immune system in reaction to the vaccine may then erroneously identify comparable self structures as foreign, attacking them in the process. Tassiulas Rep. at 2. In the context of DM, molecular mimicry would involve homology between foreign antigenic proteins and tobramycin, a muscle protein, or keratin, a protein in epidermis produced by keratinocytes. Tr. at 31; E. Walker & P. Jeffrey, *Polymyositis and Molecular Mimicry, A Mechanism of Autoimmunity*, The Lancet 605, 606–607 (1986), filed as Ex. 27, Tab E (ECF No. 38-1) ("Walker"). Walker is a review article looking at polymyositis, and found "significant homology between the hemagglutinin, that it's part of the influenza Type A, and between the hemagglutinin and the keratin and tobramycin of human origin." Tr. at 33. Walker was also focused on wild infections as causing autoimmunity rather than vaccination, but Dr. Tassiulas noted that the flu vaccine also includes hemagglutinin in a purified form. *Id.* at 35, 93–94. Dr. Tassiulas's opinion did not, however, provide a proposed homologous amino acid sequence, nor did he provide literature more specific to how DM might unfold due to the mechanism of molecular mimicry.

Dr. Tassiulas also explained how cytokine production stimulated by vaccination could lead to a pathologic process. Tr. at 37. He maintained that cells infected with the wild flu virus are known to produce interferon alpha, a cytokine that has been observed to be overexpressed in DM patients. Tassiulas Rep. at 2; Tr. at 40–41. This overexpression is not exclusive to DM, but instead is common in individuals experiencing a variety of autoimmune diseases. Tr. at 38. Such cytokine upregulation provoked by vaccination in turn has the capacity to stimulate dendritic cells in the body. *Id.* at 39. The cytokines thus lead "not only to break in tolerance but also help[] the activation

[14]An interferon can be one of many types "of glycoproteins that exert virus-nonspecific but host-specific antiviral activity by inducing the transcription of cellular genes coding for antiviral proteins that selectively inhibit the synthesis of viral RNA and proteins." *Interferon*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=25558&searchterm=interferon (last visited May 10, 2022). These interferons have immunoregulatory functions that "can be stimulated by viral infection." *Id.* Based upon the different types of interferons they are "divided into three distinct types (α, β, and γ) associated with specific producer cells and functions, but all animal cells are able to produce interferons, and certain producer cells (leukocytes and fibroblasts) produce more than one type (both interferon-α and interferon-β)." *Id.*

of lymphocytes, and also [are] one of the major factors in driving production of autoantibodies by B cells." Tr. at 57. Thus, the stimulation of these cytokines could theoretically provoke an autoimmune response.

To support this contention, Dr. Tassiulas stated that research has found that "the trivalent [vaccine] was the one that was causing this increased interferon production," compared to the monovalent vaccine. Tr. at 40. He also highlighted an article that he maintained showed the purported impact of such cytokine upregulation on individuals who had a genetic susceptibility for autoimmune disease. Tr. at 56; A. Theofilopoulos et al., *Type I Interferons (α/β) in Immunity and Autoimmunity*, 23 Ann. Rev. Immunology 307 (2005), filed as Ex. 27, Tab D (ECF No. 38-1) ("Theofilopoulos"). Theofilopoulos looked at the interferons as a type of cytokine that are crucial in the adaptive and innate immune process. *See* Theofilopoulos at 308–11. It also addresses the "potential drivers of increased Type I interferon production in diseases like lupus and what are the main mechanisms that increase Type I interferon production that can lead to autoimmune disease by breaking immune tolerance." Tr. at 56; Theofilopoulos at 310–11, 316. But as it was noted on cross-examination, Theofilopoulos does not address vaccines or vaccinations as capable of initiating this cytokine production in amounts sufficient to cause disease. Tr. at 92. Indeed, it more generally observes that this class of cytokine can *both* promote or inhibit the immune response, in positive or negative ways, with more questions than answers raised about how specifically this occurs. Theofilopoulos at 325–26.

Post-trial, Petitioner filed an additional item of literature that Dr. Tassiulas referenced in his testimony. *See* S. Athale et al., *Influenza Vaccines Differentially Regulate the Interferon Response in Human Dendritic Cell Subsets,* 22 Sci. Transl. Med. 1 (2017), filed as Ex. 45 (ECF No. 105-1) ("Athale"). Athale's authors noted the significance of dendritic cells in promoting an adaptive response to the flu vaccine and performed an experiment to compare vaccine effectiveness of two flu vaccines (the trivalent, non-adjuvanted Fluzone vaccine and the monovalent, non-adjuvanted H1N1 vaccine) in their ability to activate dendritic cells. Athale at 2–3. Athale demonstrated the Fluzone version was more effective and did so using the vaccines' ability to stimulate cytokine upregulation as a comparative measurement. *Id.* at 2, 7–8. Thus, although Athale does not say anything about DM, it is consistent with Dr. Tassiulas's argument about the significance of cytokine stimulation in immunogenicity.

Dr. Tassiulas offered other evidence to connect vaccination with autoimmune diseases like DM. Tr. at 60; R. Chen et al., *Epidemiology of Autoimmune Reactions Induced by Vaccination*, 16 J. Autoimmunity 309 (2001), filed as Ex. 27, Tab F (ECF No. 38-1) ("Chen"). Chen's authors looked at how autoimmune diseases could be triggered, with a focus on a number of different vaccines that have been associated (to varying degrees of reliability) with autoimmune conditions. *See* Chen at 310. But Chen makes no specific mention of authorities suggesting the flu vaccine is related to DM, or any arguably-comparable rheumatic condition for that matter (and in fact does

not at all discuss the flu vaccine's purported association with autoimmune conditions).

Another article observed that 9.7 percent (20 of 206) of a pool of patients experiencing some form of myopathy had previously been vaccinated, supporting a theory that the preceding vaccination could be causal. Tr. at 64; V. Limaye et al, *Infections and Vaccinations as Possible Triggers of Inflammatory Myopathies*, Muscle & Nerve 987 (2017), filed as Ex. 43 (ECF No. 101-1) ("Limaye"). Limaye considered the frequency of idiopathic inflammatory myopathies post-vaccination generally, but also considered sub-variants like DM, and found that "DM was overrepresented in those with preceding vaccination," although DM was the diagnosed subtype only in 6 of the 20 relevant cases considered. Limaye at 988. In addition, 15 of the 20 vaccinations at issue were for the flu vaccine, with a median post-vaccination onset of 10 weeks. *Id.* But Limaye's findings do not associate the flu vaccine *specifically* with DM, but instead only observed more broadly instances of myopathy after "vaccination"—without breaking down the data by specific vaccine. *Id.*[15]

The only other evidence offered by Dr. Tassiulas directly addressing an association between the flu vaccine and DM came in the form of a case report of a "68-year-old woman, apparently previously healthy, [who] after an influenza vaccination . . . developed [] basically inflammation in the muscles, at the site of vaccination, two weeks after she had the vaccine." Tr. at 62; F. Jani et al., *Influenza Vaccine and Dermatomyositis*, 12 Vaccine 1484 (1994), filed as Ex. 27, Tab G (ECF No. 38-1) ("Jani"). The woman in Jani was diagnosed with DM, and it appeared her symptoms began at the vaccination site. Jani at 1484. On cross-examination, however, Respondent observed that this was inconsistent with the more commonly-symmetrical presentation of DM. Tr. at 85, 86. Dr. Tassiulas nevertheless emphasized that Ms. Ulysse's initial presentation was consistent with the Jani case subject, although the case report (which was three paragraphs long in total) was rather lacking in detail to support the claim—and even noted specifically that "[e]pidemiological study has failed to find an association between [DM] and influenza vaccine. Jani at 1484; Tr. at 100.

Dr. Tassiulas's opinion about causation did rely to some extent on Petitioner's presentation, and he noted that she had been basically healthy pre-vaccination. Tr. at 68–69. Her workup for other potential causes was thorough as well, and looked for "evidence of recent viral infections by serological methods," but antiviral and antibiotic treatments were ineffective. *Id.* at 69–70. Ultimately, different infections were considered but nothing was deemed conclusive. *Id.* at 28. She also had workups "for occult malignancies, including mammograms, transvaginal ultrasounds . . .

[15]Limaye also noted the occurrence of a specific antibody in patients also seen in Petitioner, which Dr. Tassiulas states "is not considered to be myositis-*specific* antibody, but definitely it's a myositis-*associated* antibody." Tr. at 64 (emphasis added). Importantly, however, this antibody was only detected in Ms. Ulysse (by Dr. Tassiulas's admission) "actually a couple of years after her presentation [in the fall 2013]," making it exceedingly difficult to conclude she likely possessed it from the outset. Tr. at 14; *see also* Ex. 23 at 1–3 (February 2016 rheumatology work-up).

CP cancer test of her chest, abdomen and pelvis," but no such testing hinted at an etiology. *Id.* at 70. And she displayed no other relevant risk factors. *Id.* at 70–71.

Other alternative explanations that the record suggested were not deemed by Dr. Tassiulas to merit weight. A positive parvovirus infection test result, for example, was more likely proof of a resolved prior exposure in his view than a causal explanation. Tr. at 71. As to Ms. Ulysse's bilateral knee pain, Dr. Tassiulas noted that it was not accompanied by any description of inflammatory arthritis. *Id.* at 72. Her x-ray was also normal. And her orthopedic evaluation concluded her symptoms were likely a mechanical issue, as evidenced by the McMurray test results, which better supported a mechanical injury, despite the evidence of fluid/swelling (which he did not deem inconsistent with a non-inflammatory joint problem). *Id.* at 72–73; Ex. 10 at 1. Dr. Tassiulas also denied that systemic inflammatory arthritis could begin in one joint, but instead more commonly displayed in several joints at once—further undermining the likelihood that Petitioner's DM preceded vaccination. Tr. at 73.

On cross-examination, Dr. Tassiulas agreed that he had offered no epidemiological studies showing an association between the flu vaccine and DM—a fact that literature he filed acknowledged. Tr. at 83, 87; Orbach at 1215 ("there is no evidence in the literature that vaccines preceded IM or that IM incidence followed vaccination campaigns increased."). But because DM was a rare condition, "it's hard to have good, large epidemiological studies, and for the same reason, you know, it's hard to have good clinical therapeutic studies or control studies as well." *Id.* at 52. Instead, case reports or studies, along with retrospective studies, were in Dr. Tassiulas's estimation the best available evidence to determine potential causality. *Id.* at 53.

Finally, Dr. Tassiulas concluded that the temporal relationship between Petitioner's vaccination and onset was medically appropriate. Tr. at 76. Ms. Ulysse received the flu vaccine about two weeks before her symptoms manifested. Some of Petitioner's treaters mentioned the temporal relationship between her illness and DM, highlighting a potential association. *Id.* at 71. An onset of "weeks to some months" post-vaccination would be, in Dr. Tassiulas's estimation, medically reasonable in light of relevant authority. *Id.* at 76. Dr. Tassiulas's report referenced a case report study in which twelve cases of DM were observed to have occurred between five hours and five weeks of vaccination. Tassiulas Rep. at 5; *See* N. Agmon-Levin et al., *Vaccines and Autoimmunity*, 5 Nat. Rev. Rheumatology 648 (2009), filed as Ex. 27, Tab H (ECF No. 38-1) ("Agmon-Levin"). Agmon-Levin in fact makes no mention at all of DM (suggesting that this citation was in error). Agmon-Levin at 648–49. But a different item of literature, Orbach, referenced (in addition to the two-week timeframe for onset in Jani) JDM occurring after a variety of other vaccines, and in a timeframe of between five hours and six weeks. Orbach at 1214.

B. *Respondent's Expert: Robert W. Lightfoot, Jr., M.D.*

Dr. Lightfoot testified at the hearing and submitted one expert report addressing in writing his theory that Petitioner suffered from an atypical form of DM not caused by vaccination, and that more likely began pre-vaccination. *See* Report, filed as Ex. A on Jan. 23, 2017 (ECF No. 47-1) ("Lightfoot Rep.").

Dr. Lightfoot received his B.A. and MD. from Vanderbilt University in Nashville, Tennessee. Tr. at 111. He then did an internship at Columbia Presbyterian Medical Center, residency at Columbia Presbyterian and Vanderbilt University Hospital, finally a fellowship in rheumatology at the Columbia University College of Physicians and Surgeons. Ex. B at 1, filed on Feb. 20, 2020 (ECF No. 79-1) ("Lightfoot CV"). Dr. Lightfoot was part of the junior faculty at Cornell Medical Center for six years before becoming director of the Division of Rheumatology at the Medical College of Wisconsin. Tr. at 112.

Dr. Lightfoot is board certified in internal medicine and rheumatology. Tr. at 112; Lightfoot CV at 1. He is currently working at the University of Kentucky as a professor of medicine emeritus. Tr. at 112. He also practices rheumatology privately at his clinic and at a fellow's clinic. *Id.* Dr. Lightfoot is an active medical staff at the Albert B. Chandler Medical Center. *Id.* at 113. Dr. Lightfoot estimates he sees about 24 patients a week, along with inpatient consultation in rotation, seeing about 30 to 40 DM patients a year. *Id.* at 113–14. Further, he is a member of several professional societies. Lightfoot CV at 3–5. Dr. Lightfoot has taught and lectured on the subjects of rheumatic diseases, vasculitis, internal medicine, lupus, and other similar courses. *Id.* at 7–11. He is also published on the same topics in peer-reviewed journals, book chapters, and abstracts. *Id.* at 17–26.

Dr. Lightfoot agreed that Petitioner was properly diagnosed with DM. Tr. at 119. Based on his review of the medical record, he deemed it an atypical case, in both timing and intensity. Lightfoot Rep. at 3. He emphasized that her presentation from the start did not include the complaints of muscle weakness he would associate with DM—instead featuring pain reports and the skin-related presentation characteristic of the condition. *Id.* at 3–4. Along with this he noted that Petitioner's "serum muscle enzymes were only mildly elevated for her degree of rash and discomfort," which he also considered atypical. *Id.* at 3. Usually these would reach hundreds to thousands, but Dr. Lightfoot noted, Petitioner's "were many times in the normal range, once reaching >300, but no higher." *Id.* at 3.

Dr. Lightfoot could not identify the cause of Petitioner's DM, noting that in his experience DM's cause was more often than not unknown. *Id.* at 116. He accepted that testing evidence from the medical record did not reveal an underlying malignancy that could explain Ms. Ulysse's DM. *Id.* at 145. But he disputed that the flu vaccine could be causal, arguing that Dr. Tassiulas's evidence for this contention was unpersuasive or unsupportive. *Id.* at 121–22. Dalakas, for example, stated expressly that the etiologic explanations for inflammatory diseases remain mostly

unknown. Dalakas at 1742. Further, other studies have not found an increased risk of autoimmune diseases after vaccination. *See,* e.g., Orbach at 1215. He also disagreed with the Orbach article's listing of vaccines as an environmental factor that could cause DM, noting it included other factors that he did not find credible, like silicon implants or collagen injection. *Id.* at 143–44. Notably, Dr. Lightfoot referenced *no* literature in support of his own contentions, and only attempted to show that the literature affirmatively offered by *Petitioner* was unsupportive of her causation theory.

Dr. Lightfoot also took issue with Dr. Tassiulas's contention about the likely autoimmune nature of DM, denying that medical science had settled on an agreed autoimmune pathway to explain DM's pathologic process. Tr. at 122. Thus, while cytokine levels or certain autoantibodies could be measured in association with DM, there was no proven pathophysiology of DM that relied on either to instigate the condition. *Id.* In so proposing, Dr. Lightfoot referenced serologic testing from Petitioner's medical history, noting that her labs were almost all negative for such allegedly-causal immune cells, with the exception of one instance of an elevated autoantibody—a finding Dr. Lightfoot deemed likely to be "a spurious false positive test," given the amount of testing she underwent and its consistently negative character. Lightfoot Rep. at 4–5. There was, in his view, inadequate evidence that *in this case* Petitioner's DM was driven by cross-reactive antibodies. *Id.* at 5. Other abnormal testing results, like high liver enzymes, were results that were simply consistent with DM and thus did not corroborate the presence of an autoimmune process. Tr. at 123, 125.

It can be difficult, Dr. Lightfoot proposed, to identify onset of DM, since antibodies associated with it (which may be inadvertently observed after serologic testing) can long predate symptoms onset. Tr. at 119. Here, he opined that Petitioner's symptoms began at least a week prior to vaccination and possibly earlier. Lightfoot Rep. at 6. Thus, the flu vaccine could not be causal (whether or not it had that capacity).

To support this aspect of his opinion, Dr. Lightfoot pointed to Petitioner's medical history. Central to his determination was Petitioner's pre-vaccination orthopedic visit on September 24, 2013, when she complained of left knee problems. Tr. at 119–20; Ex. 10 at 1. The record from this visit characterized her complaints as ongoing and progressive, which in Dr. Lightfoot's view was more likely consistent with some underlying developing and chronic condition, despite other aspects of this record supporting a mechanical explanation. Tr. at 120. The x-ray on her knee was also a major factor in support of his conclusion; it was not consistent with a mechanical problem, while effusion was already detectable. Lightfoot Rep. at 6. Thereafter, and within a few weeks, this initial, arthritic presentation become more systemic, as Petitioner began experiencing symptoms in her "small joints and large joints, both right side and left side." Tr. at 120. Although he agreed that an asymmetrical presentation for DM onset was uncommon, it did not in his view rule out the likelihood that these knee symptoms established onset, since sometimes arthritis is a

major component of DM. *Id.* at 120–21, 147. He gave little weight to the evidence of crepitations as undermining his onset opinion. *Id.* at 148.

Dr. Lightfoot admitted that Ms. Ulysse's treaters had found significant the post-vaccinal nature of her injury, and in some cases proposed a connection, but he disputed whether doctors lacking expertise in immunology or rheumatology were well-suited to reliably opine on the subject. Tr. at 129. He also noted, however, that it appeared from the record that most of Ms. Ulysse's treaters (other than Dr. Levine) seemed unaware of her previous knee pain, undermining their conclusion that the vaccine was causal (since such speculation did not take into account the entire record). *Id.* at 134. Dr. Lightfoot accepted the accuracy of the McMurray test (which might corroborate a limited and mechanical problem) but noted that quickly thereafter "things got out of hand at any rate," and thus the overall findings from the September 2013 orthopedic visit were consistent with his onset opinion. *Id.* at 137. And no follow-up MRI was ever performed to confirm the possibility of a limited mechanical problem (something that in his view would have been performed by most orthopedists if they suspected that was the actual nature of the problem. *Id.* at 149.

III. Procedural History

This case was initiated in May 2015, with medical records being filed a month later, followed by an amended petition in December 2015. ECF No. 17. After expert reports were filed, a hearing had been scheduled (before the special master to whom the case had been assigned) for April 22–23, 2020, but was cancelled. Scheduling Order, dated Mar. 23, 2020 (Docket Entry). The matter was reassigned to me in January 2021 (ECF No. 94), and I reset the hearing for December 6, 2021. Prehearing Order, dated Feb. 16, 2021 (ECF No. 97). The matter proceeded as scheduled and is now ripe for resolution.

IV. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[16] In this case, Petitioner does not assert a Table claim.

[16] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121,

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden

124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V,

2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining

their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony;

or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing

Lampe, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

I. Overview of Alleged Injury

DM is characterized as a type of myositis, or an "inflammation of a voluntary muscle." *Myositis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32923 (last visited May 3, 2022). DM in particular features "inflammatory skin changes, including the Gottron sign (discolored papules, especially on extensor surfaces such as the knees, elbows, and knuckles); poikiloderma; discolored eyelids and edema of the eyelids and periorbital tissue; and an erythematous rash on the forehead, neck, trunk, and arms." *Dermatomyositis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32923 (last visited May 3, 2022). Muscle weakness is a common feature of DM. *See* Dalakas at 1735; Orbach at 1213; Jani at 1484; Limaye at 988. Focal muscle *pain*, by contrast (and distinguished from aches), is somewhat less common,

and in some cases is associated more with the injection situs rather than becoming a generalized symptom. Orbach at 1215.

Although there are very few identifiable Program decisions involving DM as an alleged flu vaccine injury, I have had occasion to consider the precise issue at least once before. *Whelan v. Sec'y of Health & Hum. Servs.*, No. 16-1174V, 2019 WL 1061473 (Fed. Cl. Spec. Mstr. Jan. 28, 2019) (denying entitlement). The *Whelan* petitioner did not go to a doctor until two months later for a dermatologist appointment, at which time she noted left shoulder pain and "frozen shoulder." *Id.* at *1. She subsequently showed signs (similar to Ms. Ulysse) of rash, Gottron's papule, and weakness in her extremities (although the *Whelan* petitioner also displayed a potential breast tumor—and hence possible evidence of malignancy). *Id.* at *1–2. The *Whelan* Petitioner's expert generally invoked the theory of molecular mimicry, along with other such as helper and suppressor T-cells, B-cell activation post-vaccination, aluminum adjuvants, and modification of antigens. *Id.* at *3. Respondent's expert, by contrast, argued that the wild flu virus had not been shown to cause DM, which should occur for the vaccine do then do such. *Id.* at *5.

I ultimately denied entitlement, but mostly due to the fact that the claimant's onset had occurred *several months* post-vaccination, and hence far longer than the relevant timeframe herein. *Whelan,* 2019 WL 1061473, at *13–14. I also noted that the petitioner's expert relied too heavily on a single case report—the same one as offered herein, Jani—and did not offer enough additional reliable evidence to associate the flu vaccine with DM. *Id.* at *15. Respondent's expert, by contrast, offered compelling reasons to doubt a vaccine association. And the "did cause" element was also unsatisfied, given (a) evidence of a potential malignant alternative cause, plus (b) reasons to question the DM diagnosis.

A different prior case resulted in a favorable determination for the petitioner—although it involved a distinguishable condition, JDM, as well as different vaccines. *Rodriguez v. Sec'y of Health & Hum. Servs.*, No. 13-253V, 2017 WL 5563419, at *1 (Fed. Cl. Spec. Mstr. Oct. 26, 2017) (granting entitlement based on Diphtheria-Tetanus-acellular Pertussis ("DTaP"), Measles-Mumps-Rubella ("MMR"), Polio, and Varicella vaccines given to a minor child). *Id.* The petitioners in *Rodriguez* put forth a theory of cytokine overproduction after administration of the vaccines, where a "pro-inflammatory interferon signature could likely cause several changes within cells, including in the endoplasmic reticulum," thereafter encouraging adaptive immune responses that would promulgate disease. *Id.* at *11. After that the adaptive immune system causes the continued responses in the body. *Id.*

In finding for petitioners, the *Rodriguez* special master was persuaded by the fact that JDM was deemed by both experts to be mediated by a combination of innate and adaptive immune responses, but with cytokines especially significant to the process. *Rodriguez,* 2017 WL 5563419, at *12. And the injured child had been exposed to several different vaccines at once (unlike the

present case), increasing the likelihood that an aberrant reaction would occur. In addition, the rarity of JDM suggested to the special master that epidemiologic studies could not shed light on causation. *Id.* In the end, both experts seemed to agree enough on the broad strokes of the theory for the special master to find that causation was preponderantly established.

II. Petitioner Has Carried her Burden of Proof

The parties do not dispute Petitioner's DM diagnosis in this case—leaving only the question of whether the flu vaccine she received likely caused it. The evidence in this case is hardly robust—but the overall mix of proof offered by Petitioner, which included reliable items of literature plus persuasive testimony by Dr. Tassiulas, crossed the preponderant line, and that showing was not rebutted by Respondent.

First, Petitioner's "can cause" showing was just adequate enough to establish preponderance. The most compelling aspect of Petitioner's theory was that cytokine upregulation attributable to vaccination could result in DM, given what is known about the role cytokines might play in DM's pathogenesis plus DM's likely autoimmune character. I am generally unpersuaded by arguments that attempt to turn around what is known about a vaccine's intended effects (and here specifically, how a vaccine may upregulate cytokines close-in-time to vaccination). *Cordova v. Sec'y of Health & Hum. Servs.*, No. 17-1282V, 2021 WL 3285367 at *17 (Fed. Cl. Spec. Mstr. June 23, 2021) ("Evidence that a vaccine causes an immune response—the intended function of any vaccine—does not amount to a showing that this response is, or can become, pathologic, absent *additional* proof linking to evidence of the vaccine's otherwise-intended response."). But in this case, Petitioner's showing (provided by a qualified expert, with specific demonstrated knowledge on both DM and the theory at issue) was supported by a reasonable mix of reliable literature and at least one on-point case study (an admittedly weak kind of evidence, but one that still requires some consideration when offered). Limaye was especially helpful to Petitioner, even though the study did not *fully* link the flu vaccine to DM, since it provided additional corroboration to the Jani single case report of observed instances in which DM occurred post-vaccination.[17]

[17]Dr. Tassiulas did not offer any epidemiologic evidence, although Petitioners can prevail in the Program without doing so (and indeed are *never obligated* to offer this kind of evidence in the first place). I do not, however, accept Dr. Tassiulas's argument that epidemiologic studies cannot meaningfully be taken into account when considering causation, given rarity of the relevant disease (and concomitantly the rarity of a vaccine-caused injury). Tr. at 52–53. That argument conflates the preponderant standard, which applies herein, with scientific certainty, which does not. Petitioners are *never* required to prove with certainty that a vaccine "can cause" an injury—but Respondent is also not burdened with proving the opposite. Thus, large scale and otherwise-reliable epidemiologic studies should not be thrown out because they cannot *disprove* causation—to require that they do so involves application of a certainty standard on only one party to a Vaccine Act claim.

The rarity of a vaccine injury is also no reason to ignore otherwise-pertinent epidemiologic proof. In effect, the argument asks the special master to give great weight to the fact that a person experienced an uncommon illness *after* vaccination—to imbue the temporal association with significance, because the fact that few get the illness in the first place means the known factor of vaccination likely caused it. Yet controlling Program law prohibits doing just that. *McGrail v. Sec'y of Health & Hum. Servs.*, No. 17-926V, 2021 WL 1728706 at *26 (Fed. Cl. Spec. Mstr. Apr. 23,

Respondent's rebuttal showing, by contrast, was far more conclusory and piecemeal. Dr. Lightfoot was certainly qualified to opine on the injury at issue, but he mostly limited his argument to attempting to show that Petitioner's DM likely predated vaccination (which, as discussed below, was ultimately not persuasive). He did successfully identify qualifications in the literature Petitioner filed, in which various authors noted the lack of full evidence either associating vaccination with DM or corroborating Petitioner's theory. But he offered *not a single item of literature*—epidemiologic studies or otherwise—to defend his contentions, preferring instead simply to maintain that the items offered by Petitioner were inadequate.[18]

This was an ineffective defense against Petitioner's showing. While no party to a Vaccine Act case is required to offer *any* particular kind of evidence, when a petitioner offers numerous items of proof in support of the first *Althen* prong, Respondent "rolls the dice" by simply trying to poke holes in the petitioner's evidence, without filing his own evidence that adds rebutting detail to the overall causation "picture." I must ultimately weigh the evidence *before me*—not what could have been offered in a more fully-litigated matter.[19] Thus, the fact that Respondent need not offer any counter-evidence does not mean that the failure to do so is not always significant. Petitioners cannot effectively rebut Respondent's employ of reliable epidemiologic evidence that undermines causation by arguing that such evidence does not "count" or need not be filed. The opposite is true as well: Respondent's failure to file his own rebuttal proof is not to be overlooked simply because he need not do so procedurally.

In the end, Petitioner's causation showing was better substantiated with a number of items of reliable scientific/medical proof, and it outweighed Respondent's more cursory rebuttal. Of course, my finding does not mean that Petitioner's showing was particularly persuasive—on the contrary, I deem it barely preponderant enough to meet her burden of proof. I make this finding despite reasoned, lingering doubt that the evidence offered in this case *proves* the flu vaccine "can cause" DM—but preponderance *does not mean scientific certainty*, so doubt can remain even in cases where a petitioner's showing is minimally adequate.

2021) ("disregarding large-scale evaluations of vaccination outcomes due to the rarity of vaccine injuries" is not reasonable). Relevant epidemiologic evidence can greatly undercut a petitioner's showing, and should be evaluated when offered, as the Circuit has noted. *See,* e.g., *D'Tiole v. Sec'y of Health & Hum. Servs.*, 726 Fed. App'x. 809 (Fed. Cir. 2018).

[18]Except in a few cases where Respondent opted not to offer his own expert in reaction to Petitioner's filing of an expert report, I can think of no other cases I have adjudicated where Respondent chose not to file a single item of literature.

[19]For this reason, I do not find that my prior decision in *Whelan* counsels against the finding in this case—putting aside the fact that no prior decisions ever compel a ruling one way or another, except in rare cases where a particular injury has been litigated so often, and so extensively, that judicial economy does not favor reconsideration (*e.g.,* claims involving autism as the alleged vaccine injury). Not only did *Whelan* involve a number of distinguishable facts (a lengthy onset in particular) that made a favorable finding impossible, but Respondent's expert showing therein was *far more persuasive*.

Second, I find that Petitioner has demonstrated preponderantly that the flu vaccine likely "did cause" her DM. As with her first prong showing, the evidence is not *strongly* in Petitioner's favor, but it is sufficient. Thus, the record in this case establishes that Petitioner complained, close-in-time to vaccination, of a malaise-like reaction (which would be consistent with the cytokine/interferon-oriented causation theory), with symptoms presentation beginning within two weeks. Although no serologic testing corroborates her causation theory, several treaters opined a vaccine association, and those opinions deserve some weight even if, as Dr. Lightfoot noted, they are not immunologic specialists. Ex. 2 at 20 (Dr. Grill, Mar. 18, 2014), 33 (Dr. Levine, Nov. 11, 2013); Ex. 5 at 2 (Dr. Lowenstein, Nov. 15, 2013); Ex. 9 at 18 (Dr. Behar, Mar. 18, 2014); Ex. 11 at 71 (Dr. Levine, May 5, 2014); Ex. 13 at 174 (Dr. Cohn, Nov. 19, 2013), 227 (Dr. Grill, Nov. 19, 2013). This also is not a case in which there is substantial evidence of a potential alternative explanation, given the negative testing results for other infectious or malignant etiologies.

The issue of onset of Petitioner's DM is admittedly problematic. The record in this case does contain evidence supporting the conclusion that Petitioner's joint issues may have begun three weeks *before* vaccination. Certainly Dr. Lightfoot made reasonable points about Ms. Ulysse's presentation at that time, and it could be inferred from it that this reflected the beginning of what later was diagnosed (and after additional manifestations) as DM. At the same time, however, the record of this pre-vaccination visit is consistent with a purely *mechanical* complaint, distinguishable from the joint pain, muscle weakness, or skin symptoms that would be consistent with DM. Those kinds of symptoms (in particular, skin rash) only manifested after vaccination, and Respondent did not persuasively establish that Petitioner's complaint of knee pain prior to vaccination was more likely than not the first onset of DM-related symptoms. Thus (and despite the fact that both experts seemed to agree Ms. Ulysse's presentation was somewhat atypical), I do not find on this record that "more likely than not" her DM preceded vaccination.

Finally, the timeframe in which Petitioner's post-vaccination symptoms manifested is consistent with her expert's theory and the support offered for it. The Jani case report and Limaye (in conjunction with evidence offered about the timeframe for cytokine upregulation, and the role those kinds of immune cells theoretically play in driving DM) all suggest that a two-week, post-vaccination onset is medically reasonable. And Dr. Lightfoot did not specifically offer testimony or written opinion establishing how or why this period of time might be too long or too short for the proposed aberrant immune reaction. Thus (and not unlike Petitioner's causation proof more generally), this aspect of Petitioner's claim was unrebutted.

CONCLUSION

As noted above, Petitioner's overall showing was not notably persuasive or strong. In a different case, with a more substantive opposition marshaled by Respondent, the outcome would likely have been different. But the evidence offered *in this case* was overall quite limited,[20] and constitutes (with the medical record evidence) the record before me. Based on that record, I find that Petitioner has carried her burden of proof, and therefore is entitled to an award of damages.

In order to guide the parties through the damages phase of the action, a separate damages order will issue.

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[20]Each side offered a single expert report, and neither exceeded six pages in length. Respondent offered no literature. And the trial was concluded in approximately a half of a day.